

WHAT IS CLAIMED IS:

1. An air temperature controlling device, comprising:

a receptacle for a self-contained power source which receptacle comprises electrical contacts;

a channel comprising an air flow path, a first opening into which air can be inhaled, and a second opening through which air is delivered to an aerosol generation device;

a heating element connected to the electrical contacts and positioned such that air flowing by the heating element flows through the channel;

10 wherein the air temperature controlling device is a hand-held, self-contained device having a total weight of 1 kilogram or less.

2. The air temperature controlling device of claim 1, further comprising:

a self-contained power source in the receptacle wherein the total weight remains 1

15 kilogram or less.

3. The air temperature controlling device of claim 2, wherein the self-contained power source is in the form of a battery having a physical size equivalent to or smaller than two standard D size electric cells.

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4. The air temperature controlling device of claim 3, wherein the battery has a physical size equivalent to or smaller than ten standard AA size cells.

25 5. The air temperature controlling device of claim 1, wherein the heating element is a wire comprised of an alloy containing copper and another metal selected from the group consisting of chromium and iron having a gauge in the range of from 16 to 36 and wherein the wire weighs from 0.5-10 grams.

6. The air temperature controlling device of claim 5, wherein the wire is formed in a coil.

7. The air temperature controlling device of claim 1, further comprising:  
5 a sensor means for measuring ambient conditions, the sensor means supplying information used to determine an amount of energy to be added to the heating element.

8. A method of creating an aerosol, comprising:  
drawing air into a channel;  
10 adding energy to a liquid formulation in a manner so as to form an aerosol wherein the formulation contains a pharmaceutically active drug and carrier and the aerosol is drawn in to the channel; and  
warming air into which the aerosol is formed in a manner so as to evaporate carrier from the particles thereby reducing particle size.

15 9. The method of claim 8, wherein the warming of the air is carried out by the application of energy in an amount of 20 Joules to 100 Joules per  $10\mu\text{l}$  of aerosolized formulation, the method further comprising:

measuring ambient conditions and warming the air based on ambient conditions.

20 10. A method of providing an aerosolized amount of particles having a size in a range of 0.5 to 12.0 microns in diameter, comprising:

drawing air through a channel;  
moving liquid formulation through a pore into air flow in the channel in a manner so as to aerosolize the formulation which comprises a liquid carrier and pharmaceutically active drug; and  
25 warming the air using a portable air temperature controlling device comprising a portable power source and heating element in an amount sufficient to evaporate liquid carrier and obtain particles having a diameter in the range of 0.5 to 12.0 microns.

11. The method of claim 10, wherein 50% or more of the carrier is evaporated away from the particles.

12. The method of claim 11, wherein substantially all the carrier is evaporated away.

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13. A method of administering a drug, comprising:

(a) determining a drug release point based on real time values of both a patient's inspiratory flow rate and inspiratory volume;

10 (b) releasing an aerosolized dose of a drug at a determined inspiratory flow rate and inspiratory volume;

(c) warming air surrounding the aerosolized formulation using a portable air temperature controlling device comprising a portable power source and a heating element;

15 (d) repeating steps (a)-(c) in a manner such the releasing repeatedly occurs at substantially the same inspiratory flow rate and inspiratory flow volume, wherein the method is carried out with the steps (a)-(d) performed by a hand-held, self-contained device.

14. The method of claim 13, wherein the portable air temperature controlling device comprises a metal wire having a size in the range of about 18 gauge to 38 gauge.

20 15. The air temperature controlling device of claim 14, wherein the metal wire is 28 gauge wire of an alloy containing nickel.

16. A method of reducing variability in aerosol drug delivery due to ambient conditions, comprising the steps of:

25 (a) warming air sufficiently to stabilize the size distribution of a generated aerosol over a range of temperatures and relative humidities likely to be encountered;

(b) generating an aerosol of an active drug from a formulation that is entrained into the warmed air;

(c) delivering the aerosol to the lungs of a subject, wherein the method is carried out by a self contained, portable device weighing 1 kilogram or less and having a volume of 50 cubic inches or less.

5        17.      The method of claim 16, wherein the warming of the air is carried out by a device powered by a power source in the form of ten or less "AA" size or similarly sized cells; wherein the air is warmed by drawing it past a heating element that is heated prior to the onset of aerosol generation; and wherein the heating element is comprised of a metal alloy comprising nickel.

10        18.      The method of claim 17, wherein the heating element is in the form of a coiled wire.

15        19.      The method of claim 17, wherein the heating element is in the form of a sheet.

20        20.      A method of delivering medication to a patient's lung comprising the steps of:

- (a) pre-heating a heating element in still air for a period of 5-60 seconds;
- (b) warming air by drawing it past the heating element for 1-10 seconds;
- (c) generating aerosol into the warmed air; and
- (d) delivering the aerosol to the patient's lungs.

25        21.      The method of claim 20, further comprising:

- (e) monitoring the heating element temperature; and heating until a preset temperature is reached; and
- (f) regulating the temperature of the heating element based on information received from a temperature sensor attached to said heating element.

22.      The method of claim 21, whereby the temperature sensor is selected from the group consisting of a thermocouple, a resistance thermometer, and a diode.

23. The method of claim 22, wherein the heating element is comprised of an alloy having a high temperature coefficient of resistance, and the temperature of the heating element is determined by measuring its resistance.

5 24. The method of claim 23, wherein the heating element is comprised of nickel-iron wire.

10 25. The method of claim 20, whereby the amount of preheating is controlled by heating the element for a predetermined period of time.

15 26. An air temperature controlling device for effecting efficiency and reproducibility of aerosol drug delivery, comprising:

- (a) a metal heating element;
- (b) a receptacle for a battery;
- (c) an aerosol generator component; and
- (d) a control circuit means for controlling the aerosol generation component in conjunction with the air temperature controlling device whereby the heating element is preheated for a period of less than 2 minutes prior to creating an aerosol, and the aerosol generation component and the air temperature controlling device combined are portable, self contained and

20 weigh less than 1.5 kg.

27. The device of claim 26, further comprising:

- (d) a battery in the receptacle wherein the battery chemistry comprises nickel and/or lithium.

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28. The device of claim 27, wherein the heating element comprises nickel.

29. The device of claim 26, wherein the device weight is less than 1 kg.

30. The device of claim 26, wherein the preheat period is less than 30 seconds.

31. The device of claim 30, wherein the control circuit means comprises a microprocessor.